

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND

GLAXO GROUP LTD.  
d/b/a/ GLAXOSMITHKLINE

Plaintiff,

v.

MICHAEL O. LEAVITT.,  
in his official capacity as  
SECRETARY, DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

and

ANDREW C. VON ESCHENBACH, M.D.  
in his official capacity as  
ACTING COMMISSIONER,  
FOOD AND DRUG ADMINISTRATION,

Defendants,

and

ROXANE LABORATORIES,

Defendant-Intervenor.

CIVIL NO. AMD 06-469

BY

FILED  
LODGED  
FEB 23 2006  
AT BALTIMORE  
CLERK U.S. DISTRICT COURT  
DISTRICT OF MARYLAND  
ENTERED  
RECEIVED  
DEPUTY

FILED

FEB 23 2006

CLERK  
DISTRICT OF MARYLAND

BY

DEPUTY

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**TEMPORARY RESTRAINING ORDER**

Upon consideration of the Complaint filed by the Plaintiff Glaxo Group Ltd. d/b/a/ GlaxoSmithKline ("GSK"), its Motion for a Temporary Restraining Order, the Memorandum in Support thereof, and having conducted a hearing on this date, and having heard opposition thereto from the Defendants and the Defendant Intervenor the Court finds that GSK has demonstrated some likelihood of success on the merits, that the balance of harms and the public interest clearly weigh in GSK's favor, and that GSK will suffer immediate and irreparable injury unless the Defendants and the

Defendant Intervenor are temporarily restrained as set forth in this Order.

Accordingly, IT IS HEREBY ORDERED pursuant to Rule 65(b) of the Federal Rules of Civil Procedure that:

- (i) Plaintiff's Motion for a Temporary Restraining Order is GRANTED;
- (ii) During the pendency of this Order, the approval and any future approval by the Food and Drug Administration of an abbreviated new drug application allowing the marketing and sale of a generic version of GSK's Flonase® Nasal Spray SHALL BE AND IS SUSPENDED; and
- (iii) The Plaintiff and PAR Pharmaceuticals shall cease the distribution of such generic product and the Plaintiff will not contract with any other company to distribute such generic product during the pendency of this Order.

IT IS FURTHER HEREBY ORDERED, pursuant to Rule 65(c) that the Plaintiff shall post a surety bond with the Clerk of the Court in the amount of \$3,000,000 by 5:00 pm February 24, 2006.

The Clerk of the Court shall provide a copy of this Order to counsel for each party on this date.

This Temporary Restraining Order shall expire at 2:00 pm on March 6, 2006.

The foregoing is Ordered this 23<sup>rd</sup> day of February 2006 at 6:47 pm.

2/23/06

C/S  
N/D in  
open Court  
cc: Fin. Dept.

/s/ Richard D. Bennett  
Richard D. Bennett  
United States District Judge